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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,036	02/18/2004	Robert Belly	VDX-5001 USNP	3966

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EXAMINER	
DRODGE, JOSEPH W	
ART UNIT	**PAPER NUMBER**
1723	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,036	BELLY ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy et al patent 5,374,522 in view of Spelsberg patent 4,307,846 (also of record) and Gautsch et al patent 6,235,501 (also of record). Murphy discloses lysing or disrupting tissues or cells that are in a container with disruption elements, in the form of

beads which roll around in the container and hence are in rolling contact with the container an ingredients therein, as a result of applied sonication (Abstract, column 14, lines 42-65, etc.), followed by removing DNA or RNA from other cellular debris by decantation and other separation steps, to extract the RNA from the sample (column 10, lines 52-65) .

The method claims firstly differ in requiring the disruption element for 45 seconds or less, although Murphy discloses that disruption and cell separation can occur rapidly or speedily, or during a time period of about one minute or less (column 14, lines 65-66) Gautsch teach that disruption elements can effect disruption of cell tissues in a manner of seconds (column 13, line 64-column 14. It would have been obvious to one of ordinary skill in the art to have operated the disruption elements of Murphy on discrete sample volumes for periods of 45 seconds or less as taught by Gautsch, so as to enable rapid or speedy processing of cell tissue and the processing of a greater total volume/quantity of cell tissue over time.

The claims also differ in requiring the addition of a nucleic acid stabilizing solution, although Murphy discloses that various reagents and processing aids can be added to the cell tissue solution being disrupted. Spelsberg also teaches the cell or tissue being disrupted is contacted in the container in a stabilizing solution (column 2, lines 35-40). Gautsch also teaches adding a solution to stabilize and homogenize any type of cell tissue being disrupted and teach that extraction of nucleic acids such as DNA or RNA, may be extracted (Abstract, column 16, line 42-column 17, line 5). It would have been obvious to one of ordinary skill in the art to have specifically added a

"nucleic acid" stabilizing solution to the material being disrupted in the Murphy method , as taught by Spelsberg amd Gautsch, to enable preservation of the RNA to enable later separation of desired nucleic acid material from the remainder of the cell tissue, since study and isolation of RNA or other nucleic acid constituents is valuable in the research and development of many medical and pharmaceutical products.

For claims 8 and 17, Gautsch teach that any of diverse cells or tissues may be disrupted including lymph cell tissue at column 16, lines 8-11.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy et al patent 5,374,522 in view of Spelsberg patent 4,307,846 (also of record) and Gautsch et al patent 6,235,501 (also of record) as applied to claims 7 and 8 above, and further in view of Hoon et al patent 6,057,105. Claims 16 and 17 further differ in requiring that the sample be obtained from the patient during the course of a surgical procedure, although Murphy discloses obtaining of samples from patients. Hoon teaches extraction of cell tissue containing RNA to be extracted from patient tissue, such as lymph node tissue [as in claim 17], during surgery (column32, lines 32-46). It would have been further obvious to one of ordinary skill in the art to have sampled tissue obtained during patient surgery, as suggested by Hoon, to facilitate timely diagnosis and treatment of diseases such as cancer.

Applicant's arguments with respect to claims 7,8,16 and 17 have been considered but are moot in view of the new ground(s) of rejection. However, some of the argument is addressed to the extent it remains pertinent to the new ground of rejection. It is generally argued that Gautsch is not obvious to combine with other prior

art of record since he is devoted to cell disruption for a continuously flowing stream rather than for batch operation conducted in containers. However, it is submitted that all of the applied prior art is commonly concerned with rapid separation of RNA or DNA from patient tissue for the purpose of preparing samples for rapid diagnosis of patient health condition or disease status.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

July 13, 2006

JOSEPH DRODGE
PRIMARY EXAMINER